

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

IN RE: REQUEST FROM VIENNA

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Misc. Case. No. 23-mc-258 (CFC)

**~~PROPOSED~~ STIPULATED PROTECTIVE ORDER**

WHEREAS, Petitioner Amgen Inc. (“Petitioner” or “Amgen”), and Respondent Sandoz Inc. (“Respondent” or “Sandoz”, and collectively with Amgen the “Parties”) expect that discovery related to the above-captioned district court case no. 23-mc-258 (CFC) (“this Proceeding”) to encompass certain information which may constitute trade secrets and/or other confidential research, development, business, or commercial information within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G) for which special protection from public disclosure and from use for any purpose other than in this Proceeding is warranted, the Parties, by and through their respective Outside Counsel, HEREBY STIPULATE to the entry of this Protective Order regarding discovery in this Proceeding.

## **DEFINITIONS**

For the purpose of this Stipulated Protective Order only:

1. “Affiliate” means a person or entity that is not a Party but that directly or indirectly through one or more intermediaries controls, or is controlled by, or is under common control with, a Party to this Proceeding.

2. “CONFIDENTIAL” means information that constitutes, contains, reveals, or reflects trade secrets or other confidential research, development, business, proprietary or commercial information within the meaning of Fed. R. Civ. P. 26(c)(1)(G), including but not limited to: nonpublic (i) scientific, regulatory, or technical information referring to, relating to, or concerning Sandoz’s BLA No. 761362, including communications with FDA relating to Sandoz’s application; (ii) scientific and technical information; (iii) financial, budgeting and/or accounting information; (iv) information about existing and potential customers; (v) past, current, or future marketing, sales, revenues, profits, forecasts, business plans, strategies, decisions, or negotiations; and (vi) personally identifying information or data, personnel compensation, evaluations, and other employment information; and includes such confidential and proprietary information about a Third Party, including any Sandoz parents, subsidiaries, and/or other Affiliates. Provisions of this Protective Order relating to CONFIDENTIAL information shall be understood to encompass any information derived from, as well as testimony and oral

conversation related to, CONFIDENTIAL information, and all copies, excerpts, and summaries thereof. CONFIDENTIAL information does not include information that is/has been:

- a. made available to the public by the Producing Party by or at the time of its production hereunder;
- b. made available to the public after the time of its production through no act, or failure to act, on behalf of the Receiving Party, its counsel, or representatives;
- c. known to such Receiving Party, or shown to have been independently developed by such Receiving Party, prior to its production herein (or its production in any other proceeding subject to a protective order or other confidentiality obligation) without the use or benefit of Discovery Material;
- d. obtained outside of this Proceeding by the Receiving Party from the Producing Party without having been designated as CONFIDENTIAL; provided, however, that this provision does not negate a protective order in another action or any other pre-existing obligation of confidentiality;

- e. previously produced, disclosed, and/or provided by the Producing Party to the Receiving Party or any Third Party without an obligation of confidentiality; or
- f. obtained by the Receiving Party from a Third Party without an obligation of confidentiality, provided the production by the Third Party did not violate this Protective Order or a protective order in another action.

3. “CONFIDENTIAL Discovery Material” means Discovery Material a Producing Party designates as CONFIDENTIAL pursuant to the terms of this Protective Order.

4. “Denosumab Products” means Prolia®, XGEVA® or any Sandoz product that includes denosumab as the active pharmaceutical ingredient.

5. “Designated Inside Counsel” means in-house attorneys that may be designated during this Proceeding pursuant to Paragraph 28.b of this Protective Order.

6. “Discovery Material” means information (regardless of how it is generated, stored or maintained) or tangible things produced by Sandoz. Discovery Material also includes deposition testimony provided by Sandoz, as well as each and every copy, compilation, abstract, summary, digest and any documents

incorporating Discovery Materials created by any recipient thereof. This Protective Order and protections herein shall apply to all Discovery Material.

7. “Expert” means a person with specialized knowledge or experience in a matter pertinent to this Proceeding or any Foreign Proceeding who has been retained by a Party or its Counsel to serve as an expert witness or as a consultant in this Proceeding or any Foreign Proceedings who, at the time of retention, is not an officer, director, or employee of a Party or an Affiliate and is not anticipated to become an officer, director, or employee of a Party or an Affiliate. Nothing in this Protective Order purports to define the term “expert” for purposes other than those addressed in this Protective Order.

8. “FDA Communications” means preparation or submission of any Citizen Petition, label modification, or use code modification to the U.S. Food & Drug Administration regarding any Denosumab Products.

9. “Foreign Proceeding” means patent infringement proceedings in the national courts of Austria or Slovenia, including proceedings seeking injunctive relief, for infringement of European patent(s) that correspond to Amgen’s patents identified in its February 10, 2023 disclosures pursuant to 42 U.S.C. § 262(l)(3)(A) based on the manufacture of a denosumab biosimilar by any Sandoz Group AG entity. Should documents produced by Sandoz give rise to any additional infringement claims, the parties agree to meet and confer in good faith on broadening

the scope of this definition, and Amgen otherwise reserves all rights to seek broadening the scope of this definition and to seek any other appropriate relief. Sandoz's agreement to meet and confer on any such proposed broadening identified by Amgen is not and should not be interpreted as an agreement by Sandoz to any broadening or that broadening is appropriate and Sandoz reserves all rights.

10. "Outside Counsel" means any attorney from a law firm whose attorneys have made a formal appearance as counsel of record for a Party in this Proceeding or have been retained to represent or advise Amgen in connection with any Foreign Proceedings and have signed Exhibit C attached hereto, and who is not an employee of a Party or an Affiliate.

11. "Party" means a party to this Proceeding.

a. "Petitioner" or "Amgen" means Amgen Inc.

b. "Respondent" means Sandoz Inc.

12. "Producing Party" means Sandoz Inc.

13. "Professional Vendor(s)" means non-attorney persons or entities retained by or for the Parties to provide litigation support services (*e.g.*, photocopying; audio or video recording; translating; preparing exhibits or demonstrations; organizing, storing, or retrieving data in any form or medium) and their employees and subcontractors.

14. “Patent Prosecution” means any participation in, direct contribution to, or indirect contribution to drafting, amending, modifying, or advising regarding the drafting, amending, or modifying of patent claims in the United States or in any other country, but does not include representing a party in connection with any post-issuance challenge to or in defense of a patent before a domestic or foreign court or agency, provided that any individual who reviews or gains knowledge of CONFIDENTIAL Discovery Material shall not be involved, either directly or indirectly, in amending claims as part of such proceeding.

15. “Protective Order” means this Stipulated Protective Order.

16. “Receiving Party” means Amgen, including its Outside Counsel.

17. “Third Party” means a person or entity that is not a Party.

### **DESIGNATION**

18. The Producing Party may designate Discovery Material as CONFIDENTIAL Discovery Material in accordance with this Protective Order only if the Producing Party in good faith believes that such Discovery Material contains CONFIDENTIAL information as defined in Paragraph 2.

19. Discovery Material shall, as appropriate, be marked by the Producing Party with a legend indicating that the Discovery Material contains a specified party’s CONFIDENTIAL Discovery Material—*i.e.*, “Respondent’s CONFIDENTIAL Discovery Material.” To the extent Discovery Material contains

CONFIDENTIAL Discovery Material of a Third Party, the legend should so identify—*i.e.*, “Third Party CONFIDENTIAL Discovery Material.” The Producing Party must use reasonable efforts to ensure that such legend appears on each page of each document or file as the format permits.

20. Testimony and information revealed during a deposition upon oral or written examination under Fed. R. Civ. P. 30 shall be treated as CONFIDENTIAL for thirty (30) days (as calculated by Fed. R. Civ. P. 6) following receipt of the final transcript by Outside Counsel for the Producing Party, but not thereafter unless, before the thirty (30) day period has expired, Counsel for the Producing Party notifies Counsel for the Receiving Party in writing that the Discovery Material set forth in the transcript is CONFIDENTIAL and identifies which Party’s CONFIDENTIAL Discovery Material is contained therein. Counsel for any Party or Third Party also may designate the transcript or portions thereof to be CONFIDENTIAL Discovery Material orally during the deposition. The appropriate legend described in Paragraph 19 shall be placed on the front of any deposition transcript (and, if recorded, any copies of the recording) containing CONFIDENTIAL Discovery Material.

21. Unless already marked, information revealed by inspection of things and premises under Fed. R. Civ. P. 34 shall be treated as though it were designated CONFIDENTIAL provided that, prior to or at any time up to thirty (30) days (as



calculated by Fed. R. Civ. P. 6) after the inspection, the Party permitting inspection specifically identifies in writing which of the Discovery Material that will be or that was disclosed by the inspection is to be designated as CONFIDENTIAL and identifies which Party's CONFIDENTIAL Discovery Material is contained therein. There will be no waiver of confidentiality, or any privilege or immunity, by the inspection of Discovery Material before it is copied and marked pursuant to this Protective Order. Inspection of Discovery Material by any Party shall be conducted by persons eligible under Paragraph 28 below.

22. Notwithstanding the other provisions of this Protective Order, a Producing Party may redact from any Discovery Material, whether or not the material has been designated as CONFIDENTIAL Discovery Material: (i) information that is subject to the attorney-client privilege, to work-product immunity, or any other applicable privilege or immunity; (ii) personally identifying information protected from disclosure by application law or regulation; and (iii) information that is not relevant to the subject matters of this Proceeding, which the Producing Party believes in good faith requires the protections under the terms of this Protective Order. By way of non-limiting example, personally identifying information may include social security number, home address, telephone number(s), sexual orientation, religion, health information, labor union affiliation, financial information, and political affiliation or similar data otherwise protected

from disclosure by state, federal, or foreign regulations. Each such redaction, regardless of size, shall be clearly labeled “Redacted–Privileged” if redacted for privilege or immunity, “Redacted – PII” if redacted for data protected from disclosure by state, federal, or foreign law or regulation related to personally identifying information, or “Redacted – Not Relevant” if redacted for lack of relevance. This Paragraph shall not be construed as a waiver of any Party’s right to seek disclosure of redacted information.

23. Material produced before the entry of this Protective Order and appropriately designated “CONFIDENTIAL pursuant to D. Del. LR 26.2” shall, upon entry of this Protective Order, instead be designated CONFIDENTIAL and handled as such under this Protective Order.

24. Any pleading, brief, declaration, affidavit, or other filing filed in this Proceeding or in any Foreign Proceeding that contains, describes, or discusses CONFIDENTIAL Discovery Material shall be filed under seal pursuant to the requirements of D. Del. LR 5.1.3 and the Court’s CM/ECF procedures or pursuant to any available procedures of the Foreign Proceeding. The filing Party must include on the cover page of the brief or other filing a descriptive legend in the following format: “CONTAINS RESPONDENT’S CONFIDENTIAL INFORMATION” or “CONTAINS THIRD-PARTY CONFIDENTIAL INFORMATION” or another suitable legend. Absent an Order of the Court providing otherwise, the sealed

material shall remain sealed. Outside Counsel for the Party filing papers containing, referring to, describing, or discussing CONFIDENTIAL Discovery Material shall be responsible for providing appropriately redacted copies of the filed document to the Court within seven days of filing a sealed document. Redacted versions of papers filed under seal shall only be made publicly available if **(a)** all CONFIDENTIAL Discovery Material is redacted; and **(b)** such redacted versions are clearly marked “Public Version,” and clearly identify each place where information or exhibits have been redacted or deleted. To the extent a Receiving Party contemplates using CONFIDENTIAL Discovery Material at a hearing in open court, the Receiving Party shall provide notice (either in writing or in open court) to the Producing Party of its intent. The Producing Party shall have an opportunity to move for an order sealing such materials before any of its CONFIDENTIAL Discovery Material may be used by another Party in a hearing in open court. In addition, this Court or any court conducting a Foreign Proceeding may enter further orders to control the use of CONFIDENTIAL Discovery Material and the conduct of hearings and trial as it relates to the use of CONFIDENTIAL Discovery Material as necessary. Amgen shall take all reasonable steps available in the jurisdiction to ensure that any CONFIDENTIAL material retains its confidentiality in Foreign Proceedings.

**USE**

25. All CONFIDENTIAL Discovery Material produced in this Proceeding shall be used by the Receiving Party solely for purposes of this Proceeding and the Foreign Proceedings, shall not be used by the Receiving Party for Patent Prosecution or any business, commercial, competitive, personal or other purpose, and shall not be disclosed by the Receiving Party to anyone other than those set forth in Paragraph 28, unless and until the restrictions herein are removed either by written agreement of counsel for the parties, or by Order of the Court or by order of a foreign court. Other than this Proceeding and the Foreign Proceedings, the Receiving Party shall not use or introduce into any other litigation or proceeding the contents of CONFIDENTIAL Discovery Material or information regarding CONFIDENTIAL Discovery Material.

26. Nothing in this Protective Order precludes a Producing Party from using or disseminating its own Discovery Material, including CONFIDENTIAL Discovery Material, for purposes other than this Proceeding.

27. At the deposition of any corporate representative designated pursuant to Fed. R. Civ. P. 30(b)(6) to testify on behalf of Sandoz on a particular topic or subject area, such witness may be shown any CONFIDENTIAL Discovery Material produced by Sandoz in this proceeding.

**DISCLOSURE OF CONFIDENTIAL DISCOVERY MATERIAL**

28. Unless otherwise directed by the Court, a foreign court, or authorized in writing by the Producing Party, CONFIDENTIAL Discovery Material may be disclosed by the Receiving Party only to the following persons:

- a. Any Outside Counsel, subject to the provisions of Paragraph 31, provided such Outside Counsel has no current responsibility or involvement in and will not have any responsibility or involvement in Patent Prosecution, as defined in Paragraph 14, of any patent or patent application claiming priority based on, or sharing a common claim of priority with, the patents in suit or any other application claiming denosumab or its uses, formulations, or methods of manufacture. The restriction described in this Paragraph shall begin when access to such CONFIDENTIAL Discovery Material is first received by the affected individual and shall end one (1) year after the final termination of this Application or the Foreign Proceedings, whichever is later.
- b. Up to four (4) Designated Inside Counsel, collectively, for Amgen, subject to the provisions of Paragraph 31, provided such Designated Inside Counsel have no current involvement, will not

have involvement in (i) Patent Prosecution, as defined in Paragraph 14, of any patent or patent application claiming priority based on, or sharing a common claim of priority with, the patents in suit or any other application claiming denosumab or its uses, formulations, or methods of manufacture, (ii) FDA Communications relating to denosumab, or (iii) any marketing, financial, pricing, or other business competitive decision-making relating to denosumab, and have signed Exhibit B attached hereto. The restrictions described in this Paragraph shall begin when access to CONFIDENTIAL Discovery Material is first received by the affected individual and shall end the earlier of (i) one (1) year after final termination of this Proceeding or the Foreign Proceedings, whichever is later, or (ii) one (1) year after a Designated Inside Counsel withdraws from representing a Party in this Proceeding and the Party that the Designated Inside Counsel represents removes him or her from its list of Designated Inside Counsel.

- c. Support personnel for attorneys listed in Paragraph 28.a and 28.b, such as discovery managers, law clerks, paralegals, secretaries, and clerical staff, assisting with this Proceeding or a Foreign

Proceeding under the supervision of an attorney described in Paragraph 28.a or 28.b

- d. Analysts, scientific advisors, and patent agents who are employees of Outside Counsel so long as they are subject to the same restrictions as Outside Counsel set forth in Paragraph 28.a.
- e. Contract attorneys retained by a Party for the sole purpose of assisting with document review in this Proceeding or any Foreign Proceeding and who shall be subject to the same restrictions as Outside Counsel set forth in Paragraph 28.a and who have signed Exhibit A attached hereto.
- f. Any Expert (as defined in Paragraph 7) who is expressly retained by a Party to assist in this Proceeding or any Foreign Proceedings, including any associates or analysts working under the supervision of the Expert, with disclosure only to the extent necessary to perform such work, subject to the provisions of Paragraph 30, and who has signed Exhibit A attached hereto.
- g. Support personnel for Experts listed in Paragraph 28.f, such as secretaries and clerical staff, assisting with this Proceeding or any Foreign Proceedings under the supervision of an Expert described in Paragraph 28.f.

- h. Any translator, interpreter, court reporter, or other shorthand reporter or typist who is translating, recording, or transcribing documents or testimony in connection with this Proceeding or any Foreign Proceeding.
- i. Professional Vendors, as defined in Paragraph 13,
- j. Personnel of this Court and any foreign court adjudicating any Foreign Proceedings, including any experts appointed by the foreign court, and all appropriate courts of appellate jurisdiction.
- k. Any other person requested by the Receiving Party and agreed to by the Producing Party in writing pursuant to the notice provision set forth below provided that any such person has signed Exhibit A attached hereto.

29. CONFIDENTIAL Discovery Material shall only be disclosed to and used by individuals permitted access to it under Paragraph 28. CONFIDENTIAL Discovery Material, copies thereof, and the information contained therein, shall not be disclosed in any manner to any other individual, until and unless (a) Outside Counsel for the party asserting confidentiality waives the claim of confidentiality, or (b) the Court orders such disclosure.

30. As a condition precedent to disclosure of CONFIDENTIAL Discovery Material to an individual described above in Paragraph 28.f, at least ten (10) days



(as calculated by Fed. R. Civ. P. 6) before the disclosure of the CONFIDENTIAL Discovery Material is made, Outside Counsel for the Receiving Party shall serve a Notice on the Producing Party identifying such individual by name and including a curriculum vitae (“CV”) or equivalent résumé disclosing the individual’s employment history, past or present contractual relationship with any of the Parties and Affiliates, all cases in which the individual has testified in a deposition or a trial in the past five (5) years, and an executed acknowledgment from the individual to whom the disclosure is to be made, in the form of Exhibit A attached hereto. For purposes of this disclosure requirement, attendance at a Party sponsored conference does not constitute a “relationship” that must be disclosed. If a Producing Party objects to the proposed disclosure to such individual within ten (10) days (as calculated by Fed. R. Civ. P. 6) of receiving Notice, the Parties shall confer within two (2) days of the objection by the Producing Party to, in good faith, resolve the concerns giving rise to the objection. Any such objection must set forth in detail the grounds on which such objection is based. If the Parties are unable to reach agreement regarding such disclosure, the objecting Party must apply to the Court for a protective order no later than seven (7) days (as calculated by Fed. R. Civ. P. 6) after the parties have conferred and failed to agree on a resolution. The burden shall be on the objecting Party to demonstrate to the Court why such individual should not be permitted to receive CONFIDENTIAL Discovery Material under the

Protective Order. CONFIDENTIAL Discovery Material shall not be disclosed to such individual pending the Court's resolution of the dispute. The foregoing ten (10), two (2), and seven (7) day periods may be extended or shortened by agreement of the Parties or by Order of the Court.

31. As a condition precedent to disclosure of CONFIDENTIAL Discovery Material to an individual described above in Paragraph 28.b, at least five (5) days (as calculated by Fed. R. Civ. P. 6) before the disclosure of the CONFIDENTIAL Discovery Material is made, Outside Counsel for the Receiving Party shall serve a Notice on the Producing Party including an executed acknowledgment from the individual to whom the disclosure is to be made, in the form of Exhibit B attached hereto for an individual described above in Paragraph 28.b. If a Producing Party objects to the proposed disclosure to such individual within five (5) days (as calculated by Fed. R. Civ. P. 6) of receiving Notice, the Parties shall confer within two (2) days of the objection by the Producing Party to, in good faith, resolve the concerns giving rise to the objection. Any such objection must set forth in detail the grounds on which such objection is based. If the Parties are unable to reach agreement regarding such disclosure, the objecting Party must apply to the Court for a protective order no later than three (3) days (as calculated by Fed. R. Civ. P. 6) after the parties have conferred and failed to agree on a resolution. The foregoing five (5), two (2), and three (3) day periods may be extended or shortened by

agreement of the Parties or by Order of the Court. The same procedures set forth in this Paragraph shall also apply to Outside Counsel who has been retained to represent or advise Amgen in connection with any Foreign Proceedings, except that the Receiving Party need only provide notice to the Producing Party identifying Outside Counsel's law firm, provide the Producing Party with an executed copy of Exhibit C from at least one senior or supervising attorney from each such law firm, and provide an acknowledgement that any Outside Counsel at that law firm to be provided access to CONFIDENTIAL Discovery Material will abide by this Protective Order and will execute the form of Exhibit C attached hereto. The Receiving Party will be responsible for maintaining executed copies of Exhibit C and shall provide copies to Producing Party upon a showing of good cause.

32. During the pendency of this Proceeding and any Foreign Proceedings, a Party may replace a Designated Inside Counsel with a new designee. The individuals identified as Designated Inside Counsel may be substituted for another individual Inside Counsel if and when the Designated Inside Counsel departs the company or another situation arises that necessitates substitution. As a condition precedent to disclosure of CONFIDENTIAL Discovery Material to the new designee, at least five (5) days (as calculated by Fed. R. Civ. P. 6) before the disclosure of the CONFIDENTIAL Discovery Material is made, Outside Counsel for the Receiving Party shall serve a Notice on the Producing Party including an

executed acknowledgment from the new designee, in the form of Exhibit B attached hereto, and the identification of the Designated Inside Counsel that is to be replaced by the new designee. If a Producing Party objects to the proposed disclosure to the new designee within five (5) days (as calculated by Fed. R. Civ. P. 6) of receiving Notice, the Parties shall confer within two (2) days of the objection by the Producing Party to, in good faith, resolve the concerns giving rise to the objection. Any such objection must set forth in detail the grounds on which such objection is based. If the Parties are unable to reach agreement regarding such disclosure, the objecting Party must apply to the Court for a protective order no later than three (3) days (as calculated by Fed. R. Civ. P. 6) after the parties have conferred and failed to agree on a resolution. The foregoing five (5), two (2), and three (3) day periods may be extended or shortened by agreement of the Parties or by Order of the Court.

33. Counsel must maintain a copy of the executed Exhibit A, Exhibit B, or Exhibit C attached hereto for each individual falling under Paragraphs 28.a, 28.b, 28.e, or 28.j, during the Litigation and for a period of one year thereafter.

34. The recipient of any CONFIDENTIAL Discovery Material that is provided under this Protective Order (including any copies or excerpts made thereof) shall maintain such information in a secure and safe area and shall exercise reasonable and proper care with respect to the storage, custody, use, and dissemination of such information. The recipient of CONFIDENTIAL Discovery

Material produced in electronic form shall maintain such CONFIDENTIAL Discovery Material on a secure, password-protected computer, drive, or server with access restricted to persons authorized under Paragraph 28.

**EXEMPTED MATERIALS, OBJECTION TO DESIGNATIONS, AND  
INADVERTENT DISCLOSURE**

35. Amgen may object to the designation by the Producing Party of any Discovery Material as CONFIDENTIAL. The process for making an objection to the designation of Discovery Material as CONFIDENTIAL and for resolving the dispute shall be as follows:

- a. Counsel for the Receiving Party shall notify Outside Counsel for the Producing Party in writing as to its objection(s) to the designations. This notice shall include, at a minimum, a specific identification of the designated CONFIDENTIAL Discovery Material as well as the reasons for the objection.
- b. Counsel for the Receiving Party shall thereafter have the burden of promptly (and in no case later than five (5) days (as calculated by Fed. R. Civ. P. 6) after objections being provided pursuant to Paragraph 35.a) seeking to confer either in person or by telephone with Outside Counsel for the Producing Party claiming protection (as well as any other interested Third Party) in a good-faith effort to resolve the dispute pursuant to D. Del. LR 7.1.1.

- c. If a dispute as to a designation of CONFIDENTIAL Discovery Material cannot be resolved by agreement, the proponent of the designation being challenged shall present the dispute to the Court by contacting the Court's case manager in accordance with the discovery dispute procedures set forth in paragraph 6 the Court's Form Rule 16 Scheduling Order for Non-Patent Cases – Revised March 2, 2020. The Receiving Party bears the burden to establish that the Discovery Material is not CONFIDENTIAL as defined in Paragraph 2 and not entitled to such protection under this Protective Order. The document or information that is the subject of the challenge shall be treated as originally designated pending resolution of the challenge.

36. Notwithstanding any such challenge to the designation of Discovery Material as CONFIDENTIAL, all such material so designated shall be treated as such and shall be subject to the provisions of this Protective Order until one of the following occurs: **(a)** the Party which designated the material as CONFIDENTIAL withdraws such designation in writing, or **(b)** the Court rules that the designation is not proper and that the designation be removed.

37. If Amgen learns that, by inadvertence or otherwise, it has disclosed Discovery Material to any person or in any circumstance not authorized under this

Protective Order, Amgen must within five (5) days (a) notify Sandoz in writing of the unauthorized disclosures and provide all known relevant information concerning the nature and circumstances of the disclosure, (b) use its best efforts to retrieve all unauthorized copies of the Discovery Material and ensure that no further or greater unauthorized disclosure and/or use thereof is made, (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Protective Order, and (d) request such person or persons to execute the “Declaration to be Bound by Protective Order” attached as Exhibit A.

### **NO WAIVER OF PRIVILEGE**

38. Pursuant to Fed. R. Evid. 502(d) and Fed. R. Civ. P. 26(b)(5), the production of documents subject to the attorney-client privilege or the work-product immunity, or any other privilege or immunity, will not waive the attorney-client privilege, work-product immunity, or other privilege or immunity in this Proceeding or in any other federal, state or foreign proceeding. For example, the mere production of privileged or work-product-protected information in this Proceeding as part of a production is not itself a waiver in this Proceeding or in any other federal, state, or foreign proceeding. Further, the fact that information was produced shall not be used in any manner as evidence in support of any such alleged waiver. If a Party has produced information subject to a claim of privilege or immunity, upon request identifying such information (“Recalled Information”), the information and

all copies thereof shall be returned promptly, or a signed verification by Outside Counsel for the Receiving Party certifying that all such information and copies have been destroyed shall be provided to Outside Counsel for the Producing Party no later than ten (10) days (as calculated by Fed. R. Civ. P. 6), after a request is made by the Producing Party, as required by Fed. R. Civ. P. 26(b)(5)(B). Moreover, any notes or summaries, other than those expressly permitted under this section, referring to or relating to any Recalled Information subject to a claim of privilege or immunity shall be destroyed. Nothing herein shall prevent the Receiving Party from preparing a record for its own use containing the date, author, address(es), and such other information as is reasonably necessary to identify the Recalled Information and generally describe its nature and subject matter sufficient to show the alleged non-privileged information to the Court in any motion to compel production of the information. Such a record of the identity, nature, and subject matter of such information may not be used for any purpose other than preparation of an application to compel the Recalled Information in this Litigation. After the return or destruction of Recalled Information, the Receiving Party may challenge the Producing Party's claim(s) of privilege or immunity by making an application to the Court after the Parties have met and conferred pursuant to D. Del. LR 7.1.1.

39. If Amgen receives information that Amgen believes may be subject to a claim of privilege or protection from discovery, Amgen shall identify the



information to Sandoz promptly, and in any case within five (5) days (as calculated by Fed. R. Civ. P. 6). When Amgen identifies such privileged or protected information, Amgen will return the information and all copies thereof promptly, or provide a signed verification by Outside Counsel certifying that all such information and copies have been destroyed shall be provided to Sandoz's Outside Counsel no later than ten (10) days (as calculated by Fed. R. Civ. P. 6), after a request is made by the Producing Party, as required by Fed. R. Civ. P. 26(b)(5)(B). Moreover, any notes or summaries, other than those expressly permitted under this section, referring to or relating to any Recalled Information subject to a claim of privilege or immunity shall be destroyed. After the return or destruction of Recalled Information, the Receiving Party may challenge the Producing Party's claim(s) of privilege or immunity by making an application to the Court after the Parties have met and conferred pursuant to D. Del. LR 7.1.1.

40. Amgen may seek to compel the production of information identified by Sandoz as privileged or protected on the basis that: (a) the information was never privileged or protected from disclosure; or (b) any applicable privilege or immunity has been waived by some act other than inadvertent production of the information in this Action. Any such request shall not disclose or otherwise use the content of the inadvertently produced document or information (beyond any information appearing on a privilege log) in any way. The Parties expressly acknowledge that

documents which were inadvertently or unintentionally produced cannot be sequestered by Amgen for submission to the Court or in the Foreign Proceeding. Outside Counsel for Sandoz and Outside Counsel for Amgen shall meet and confer in accordance with applicable law or Court rules regarding any such request to compel production.

### **FAILURE TO DESIGNATE**

41. The failure by a Producing Party to designate Discovery Material as CONFIDENTIAL shall not be a waiver of such designation provided that the Producing Party that fails to make such designation informs the Receiving Party that such Discovery Material is CONFIDENTIAL promptly but not more than fifteen (15) days (as calculated by Fed. R. Civ. P. 6) after the failure to designate first became known to the Producing Party. The failure by a Producing Party to designate Discovery Material as CONFIDENTIAL shall not preclude the filing of an application with the Court at a later date seeking to impose such designation or challenging the propriety thereof. The Receiving Party in receipt of Discovery Material that the Producing Party failed to designate as CONFIDENTIAL shall not be in violation of this Protective Order for any use made of such Discovery Material before the Receiving Party is informed of the failure to designate. Once the Receiving Party has been informed of the failure to designate pursuant to this Paragraph, the Receiving Party shall take reasonable steps to, at the Producing

Party's option, either ensure that all copies of any such Discovery Materials are returned promptly to the Producing Party or ensure that all copies of any such Discovery Materials are marked with the proper designation and distributed only as permitted under this Protective Order.

42. In the event of disclosure of CONFIDENTIAL Discovery Material to any person not authorized to such access under this Protective Order, the Party responsible for having made such disclosure, and each Party with knowledge thereof, shall immediately inform Outside Counsel for the Party whose CONFIDENTIAL Discovery Material has been disclosed of all known relevant information concerning the nature and circumstances of the disclosure. The Party responsible for improperly disclosing such CONFIDENTIAL Discovery Material shall also promptly take all reasonable measures to retrieve the improperly disclosed CONFIDENTIAL Discovery Material and to ensure that no further or greater unauthorized disclosure and/or use thereof is made.

#### **RETURN/DESTRUCTION OF MATERIALS**

43. Not later than ninety (90) days (as calculated by Fed. R. Civ. P. 6) after the termination of any Foreign Proceedings initiated by February 1, 2025, or February 1, 2025 if no Foreign Proceedings have been initiated by then, all CONFIDENTIAL Discovery Material, including all copies thereof, shall be returned to the Producing Party or destroyed, such election to be made by the Receiving Party.

Notwithstanding the requirements elsewhere in this Paragraph, each Party may retain one (1) archival copy of all papers filed with the Court, expert reports, discovery responses, transcripts of testimony and exhibits, correspondence, mediation briefs, and their own work product containing such Discovery Material, and provided that such Party, and their respective Outside Counsel, Designated Inside Counsel, and their respective employees shall not disclose any Party's CONFIDENTIAL Discovery Material contained therein to any person or entity except pursuant to a written agreement with the Producing Party or as otherwise provided in this Protective Order and shall maintain the safeguards set forth in Paragraph 34. Outside Counsel, Designated Inside Counsel, and its respective employees need not purge back-up systems, provided, however, that any CONFIDENTIAL Discovery Material contained in such documents retained by Designated Inside Counsel or Outside Counsel shall remain subject to the protections of this Protective Order. Not later than ninety (90) days (as calculated by Fed. R. Civ. P. 6) after the termination of the Foreign Proceedings, the Party receiving any CONFIDENTIAL Discovery Material shall certify in writing to the Producing Party that all such material has been returned or destroyed.

**FILING OF DESIGNATED DISCOVERY MATERIAL IN A FOREIGN  
PROCEEDING**

44. Amgen shall redact, in good faith, any information in Discovery Materials submitted in any Foreign Proceeding that is not relevant and material to

its argument in the Foreign Proceeding, unless it is relevant for understanding the context of the document. As set forth in Paragraph 24, any pleading, brief, declaration, affidavit, or other filing filed in any Foreign Proceeding that contains, describes, or discusses CONFIDENTIAL Discovery Material shall be filed under seal pursuant to available procedures in the Foreign Proceeding. Amgen shall take all reasonable steps available in the jurisdiction to ensure that any CONFIDENTIAL material retains its confidentiality in Foreign Proceedings.

#### **PERSONAL DATA SUBJECT TO THE GDPR**

45. The Parties acknowledge that disclosure and discovery activity in this Proceeding or any Foreign Proceeding may involve production of information that may be subject to the General Data Protection Regulation No. 2016/679 of the European Parliament (“GDPR”), and that Article 44 of the GDPR limits transfers of personal data. The Parties further acknowledge that, under Article 49 of the GDPR, information subject to the regulation may be transferred where such information is “necessary for the establishment, exercise or defence of legal claims.” (GDPR Art. 49 (1)(e)).

46. Sandoz shall redact any Sensitive Personal Data subject to the GDPR. Sandoz shall label any such redacted information as “PII REDACTION” or similar designation. Amgen may inquire as to the nature of the redacted information to the extent necessary to allow consideration of the appropriateness of the redaction. In

the event there is a dispute concerning the relevance of redacted Sensitive Personal Data, the Parties shall meet and confer in good faith.

47. In the event that Sandoz determines that it has inadvertently disclosed Sensitive Personal Data or other Personal Data without the appropriate designation or redaction, it shall promptly alert Amgen. In the event that Amgen determines that Sandoz has disclosed Sensitive Personal Data or other Personal Data without the appropriate designation or redaction, it shall promptly alert Sandoz and any individuals in possession of the information. In either situation, Sandoz shall promptly produce a new version of the document or other evidence with the appropriate designation or redaction, and Amgen shall delete and destroy all copies of the originally-produced document.

48. Any Protected Material containing information or data subject to the GDPR to be filed with the Court shall be filed in accordance with above procedures for filing protective material under seal.

### **MISCELLANEOUS PROVISIONS**

49. Nothing in this Protective Order shall be deemed to bar or preclude any Producing Party from seeking additional protections, including, without limitation, an order that certain information may not be discovered at all.

50. The entry of this Protective Order shall not be construed as a waiver of any right to object to the furnishing of information in response to discovery, and

except as expressly provided, shall not relieve any party of the obligation of producing information in the course of discovery.

51. If Amgen is served with a subpoena or a court order issued in other litigation that compels disclosure of any information or items designated in this Action as CONFIDENTIAL, Amgen must, prior to disclosure of the designated information or items:

- a) promptly notify Sandoz in writing. Such notification shall include a copy of the subpoena or court order;
- b) promptly notify in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Protective Order. Such notification shall include a copy of this Stipulated Protective Order; and
- c) cooperate with respect to all reasonable procedures sought to be pursued by Sandoz.

52. If Sandoz timely seeks a protective order, Amgen shall not produce any information designated in this Action as CONFIDENTIAL before a determination by the court from which the subpoena or order issued, unless Amgen has obtained Sandoz's permission. Sandoz shall bear the burden and expense of seeking protection in that court of its confidential material.

53. If Sandoz does not seek a protective order within twenty (20) days of the date written notice is given, Amgen may produce, on or after the date set for production in the subpoena or other request, but not prior to the end of the 20 (20) day notice period, such material in response thereto, under a protective order with confidentiality provisions equal to or more restrictive than those of this Protective Order.

54. Other Proceedings. By entering this Protective Order and limiting the disclosure of information in this Proceeding, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any Receiving Party or Third Party subject to this Protective Order who becomes subject to a motion to disclose a Producing Party's CONFIDENTIAL Discovery Material designated as such pursuant to this Protective Order shall promptly notify the Producing Party of the motion so that the Producing Party may have the opportunity to appear and be heard on whether that CONFIDENTIAL Discovery Material should be disclosed.

55. Outside Counsel shall have the right to exclude from depositions, other than the deponent, the reporter, and the videographer (if any), any person who is not authorized under this Protective Order to receive CONFIDENTIAL Discovery Material. Such right of exclusion shall be applicable only during periods of examination or testimony directed to CONFIDENTIAL Discovery Material. The



failure of individuals other than the deponent, the reporter, and the videographer (if any), to leave the deposition room during any portion of the deposition that inquiries into matters designated CONFIDENTIAL by the designating party shall constitute justification for Outside Counsel to call the Court to have the issue resolved.

56. All notices during this Proceeding and the Foreign Proceedings required by this Protective Order are to be made by email to a Party's Outside Counsel (including, if available, to Outside Counsel's service distribution email address designated for this Proceeding) and all notices subsequent to the termination of this Proceeding and the Foreign Proceedings are to be made by email and U.S. mail to a Party's Outside Counsel and the office of the Party's general counsel. The date by which a Party receiving notice shall respond or otherwise take action shall be computed from the date the Party's Outside Counsel, the Party's Designated Inside Counsel, or the Party's general counsel first receives the notice via either email, U.S. mail, FedEx or UPS sent and addressed as required under this Paragraph. Any of the notice requirements herein may be waived in whole or in part, but only in writing signed by Counsel for the Producing Party.

57. Nothing in this Protective Order shall bar or otherwise restrict any Outside Counsel or Designated Inside Counsel from rendering advice to his or her client with respect to this Proceeding or any Foreign Proceedings and, in the course thereof, relying in a general way upon his or her examination of CONFIDENTIAL

Discovery Material produced or exchanged in this Proceeding; provided, however, that in rendering such advice and in otherwise communicating with a person not permitted access to CONFIDENTIAL Discovery Material under this Protective Order, the Outside Counsel or Designated Inside Counsel shall not disclose the contents of CONFIDENTIAL Discovery Material produced by any other Party or Third Party.

58. Execution of this Protective Order shall not constitute a waiver of the right of any Party to claim in this Proceeding or otherwise that any document, communication, or any portion thereof, is privileged or otherwise non-discoverable, or is not admissible in evidence in this Proceeding or any other proceeding.

59. This Protective Order may be amended by the agreement of Outside Counsel for the Parties in the form of a written Stipulated Amended Protective Order signed by each Party's Outside Counsel and filed with the Court for approval. This Protective Order is being entered without prejudice to the right of any party to move the Court for modification or for relief from any of its terms. The Court retains the authority to allow disclosure of any subject or CONFIDENTIAL Discovery Material covered by this Protective Order or to modify or vacate this Protective Order at any time in the interest of justice.

60. Neither the termination of this Proceeding nor the termination of employment of any person with access to any CONFIDENTIAL Discovery Material

shall relieve a Party from the obligation of maintaining the confidentiality of such information in accordance with this Protective Order. The Court shall retain jurisdiction after final termination of this Proceeding **(a)** to interpret and enforce the terms of this Protective Order and **(b)** to make such modifications, amendments, deletions and additions to this Protective Order as the Court may deem appropriate.

61. After August 1, 2024, Amgen shall not seek further discovery from Sandoz in connection with this Proceeding absent good cause and Sandoz shall not otherwise be obligated to provide further discovery in connection with this Proceeding absent party agreement or court order.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP    SHAW KELLER LLP

*/s/ Brian P. Egan*

*/s/ Andrew E. Russell*

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Jack B. Blumenfeld (#1014)  
 Brian P. Egan (#6227)  
 Cameron P. Clark (#6647)  
 1201 North Market Street  
 P.O. Box 1347  
 Wilmington, DE 19899  
 (302) 658-9200  
 jblumenfeld@morrisnichols.com  
 began@morrisnichols.com  
 cclark@morrisnichols.com

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Karen E. Keller (#4489)  
 Andrew E. Russell (#5382)  
 Emily S. DiBenedetto (#6779)  
 1105 North Market Street  
 Wilmington, DE 19801  
 (302) 298-0702  
 kkeller@shawkeller.com  
 arussell@shawkeller.com  
 edibenedetto@shawkeller.com

*Attorneys for Applicant Amgen Inc*

*Attorneys for Respondent Sandoz, Inc.*

IT IS SO ORDERED.

Dated: 11/14/2023

/s/ Colm F. Connolly  
Chief, United States District Judge

**EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

IN RE: REQUEST FROM VIENNA

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Misc. Case. No. 23-mc-258 (CFC)

**AGREEMENT TO BE BOUND BY THE PROTECTIVE ORDER**

I, \_\_\_\_\_, declare under penalty of perjury that:

1. My address is \_\_\_\_\_.
2. My present employer is \_\_\_\_\_ and the address of my present employment is \_\_\_\_\_.
3. My present occupation or job description is \_\_\_\_\_.
4. I have received and carefully read the Protective Order in this Proceeding dated \_\_\_\_\_, 2023 and understand its provisions. I agree
  - (i) to be bound by the terms of the Protective Order;
  - (ii) to use CONFIDENTIAL Discovery Material solely for the purposes delineated within the Protective Order; and
  - (iii) to not disclose any CONFIDENTIAL Discovery Material to any person, firm, corporation or other entity not qualified to have access to such information pursuant to the terms of the Protective Order.

5. I will return or destroy all CONFIDENTIAL Discovery Material at the relevant time in accordance with Paragraph 43 of the Protective Order.

6. I hereby submit to the jurisdiction of the United States District Court for the District of Delaware for the purpose of enforcement of the Protective Order. I understand that if I violate the provisions of the Protective Order, I will be in violation of a Court Order and subject to sanctions or other remedies that may be imposed by the Court and may be liable in a civil action by one or more of the parties in this action.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: \_\_\_\_\_

Signature: \_\_\_\_\_

**EXHIBIT B**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

IN RE: REQUEST FROM VIENNA

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Misc. Case. No. 23-mc-258 (CFC)

**AGREEMENT TO BE BOUND BY THE PROTECTIVE ORDER**

I, \_\_\_\_\_, declare under penalty of perjury that:

1. My address is \_\_\_\_\_.
2. My present employer is \_\_\_\_\_ and the address of my present employment is \_\_\_\_\_.
3. My present occupation or job description is \_\_\_\_\_.
4. I have received and carefully read the Protective Order in this Proceeding dated \_\_\_\_\_, 2023 and understand its provisions. I agree
  - (i) to be bound by the terms of the Protective Order;
  - (ii) to use CONFIDENTIAL Discovery Material solely for the purposes delineated within the Protective Order;
  - (iii) to not disclose any CONFIDENTIAL Discovery Material to any person, firm, corporation or other entity not qualified to have access to such information pursuant to the terms of the Protective Order; and that

(iv) I meet the requirements for Designated Inside Counsel as set forth in Paragraph 28.b of the Protective Order.

5. I will return or destroy all CONFIDENTIAL Discovery Material at the relevant time in accordance with Paragraph 43 of the Protective Order.

6. I hereby submit to the jurisdiction of the United States District Court for the District of Delaware for the purpose of enforcement of the Protective Order. I understand that if I violate the provisions of the Protective Order, I will be in violation of a Court Order and subject to sanctions or other remedies that may be imposed by the Court and may be liable in a civil action by one or more of the parties in this action.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: \_\_\_\_\_

Signature: \_\_\_\_\_



**EXHIBIT C**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

IN RE: REQUEST FROM VIENNA )  
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 ) Misc. Case. No. 23-mc-258 (CFC)  
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**AGREEMENT TO BE BOUND BY THE PROTECTIVE ORDER**

I, \_\_\_\_\_, declare under penalty of perjury that:

1. My address is \_\_\_\_\_.
2. My present employer is \_\_\_\_\_ and the address of my present employment is \_\_\_\_\_.
3. My present occupation or job description is \_\_\_\_\_.
4. I have received and carefully read the Protective Order in this Proceeding dated \_\_\_\_\_, 2023 and understand its provisions.
5. I have been retained to represent or advise Amgen in connection with a Foreign Proceeding as defined in the Protective Order.
6. I agree:
  - (i) to be bound by the terms of the Protective Order;
  - (ii) to use CONFIDENTIAL Discovery Material solely for the purposes delineated within the Protective Order;
  - (iii) to not disclose any CONFIDENTIAL Discovery Material to any person, firm, corporation or other entity not qualified to have

access to such information pursuant to the terms of the Protective Order; and that

(iv) I meet the requirements for Outside Counsel as set forth in Paragraph 28.a of the Protective Order.

7. I will return or destroy all CONFIDENTIAL Discovery Material at the relevant time in accordance with Paragraph 43 of the Protective Order.

8. I hereby submit to the jurisdiction of the United States District Court for the District of Delaware for the purpose of enforcement of the Protective Order. I understand that if I violate the provisions of the Protective Order, I will be in violation of a Court Order and subject to sanctions or other remedies that may be imposed by the Court and may be liable in a civil action by one or more of the parties in this action.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: \_\_\_\_\_

Signature: \_\_\_\_\_